

"Claimants object to these interrogatories mainly on the ground that they 'represent an attempt to secure the results of work performed by experts who are generally, and particularly in Food and Drug cases, shielded from interrogation by the opposing party.' The libellant argues that the interrogatories are directed towards obtaining information concerning the work of experts who should have been employed by the claimants even before the case arose and that they are relevant. The general rule in situations such as this is perhaps best expressed by Moore in *Moore's Federal Practice*, Sec. 26.24, p. 1158, who writes:

The court should not ordinarily permit one party to examine an expert engaged by the adverse party, or to inspect reports prepared by such experts, in the absence of a showing that the facts or the information sought are necessary for the moving party's preparation for trial and cannot be obtained by the moving party's independent investigation or research.

"Although the Government has not made an express or affirmative showing that this information is necessary for preparation for trial and cannot be obtained by its independent investigation or research, yet a main issue in the case is whether the claims made of 'Tranquilease' are false and misleading. The questions propounded by the libellant are directed to tests, if any, and experts, if any, that will support the position of the claimants on the issue of whether the claims made for the article are false or misleading. It appears from the questions themselves that they are requesting matter of such a nature that it is within the possession or knowledge of the claimants only and that the libellant can in no way obtain such information through independent investigation or research. In the case of *U.S. v. 132 Cartons \* \* \* Chloresium Tooth Paste*, decided March 27, 1950, U.S.D.C. for Dist. of Connecticut, Judge Hincks wrote the following:

\* \* \* I have come to the conclusion that to facilitate its cross-examination of claimant's witnesses and to prepare its rebuttal to claimant's defense the government is entitled to the discovery through the proposed deponents which it names of all matters not privileged. \* \* \* Libellant insisted that the discovery was necessary not to elicit their opinions as experts but rather to ascertain the factual scope and nature of the research done so that it possibly may be in a better position to cross-examine these witnesses on trial and prepare a rebuttal to the claimant's defense. Having in mind that the field in question here is one of scientific controversy wherein without prior discovery cross-examination cannot be expected successfully to perform its historic function, and effective evidence in rebuttal, though perhaps in existence, cannot be produced forthwith upon the close of the claimant's defense, I feel that here there is sufficient showing of necessity, within the rule of *Hickman v. Taylor* if applicable here, to allow the discovery to proceed.

"Based upon the issues involved, the need of the Government for the desired information, the lack of other sources, and the foregoing authority, this Court hereby overrules objections to Interrogatories Nos. 11 and 12.

"Counsel will submit order."

An order was entered in accordance with the opinion and the interrogatories were answered by the claimants. Thereafter, the Government filed a motion for summary judgment. On 10-20-59, the claimants filed a motion to withdraw their claim and answer. On 10-29-59, an order was entered by the court withdrawing claimant's claim and answer and directing that the article be condemned and destroyed. On 11-16-59, the article was destroyed.

6214. Vi-San Food Supplement. (F.D.C. No. 42462. S. Nos. 36-446 M, 11-762 P, 11-769 P.)

INFORMATION FILED: 4-27-59, S. Dist. Calif., against Vi-San Nutritional Laboratories, a corporation, Burbank, Calif.

SHIPPED: Between 9-27-57 and 3-25-58, from Burbank, Calif., to Detroit, Mich.

**LABEL IN PART:** (Box) "VI-SAN Food Supplement THERAPEUTIC, \* \* \* Contents 60 Red Vitamin Capsules 180 Green Mineral Tablets \* \* \* Manufactured by the Vi-San Nutritional Laboratories, Burbank, California."

**ACCOMPANYING LABELING:** Phonograph records designated "Vi-San Nutritional Laboratories Your Priceless Possession" and "Vi-San Recording Prescription For Better Living"; pamphlet entitled "Record O Gram"; booklet entitled "Your Priceless Possession"; folder designated "Marketing Plan" consisting of a booklet entitled "Marketing Plan Distributor Record-Keeping System" and a small folder headed "Coffee Cup Career"; folder designated "The Atomic You" consisting of booklets entitled "The Vi-San Story" and "Why Millions of Americans"; folders entitled "For You The Very Best," "Live Lively," "Prescription for Better Living," "Mink Coats for Vi-San Minerals," "Why Feel Old?" and "A Report On The Health Of The Nation"; a box label which purported to describe the contents of the enclosed capsules and tablets; a statement on the lid of the plastic container enclosed in the box; and an insert card in the plastic container which purported to describe the composition of the capsules and tablets.

**CHARGE: 502(a)**—when shipped: (a) the labeling of the article contained false and misleading representations that the article was adequate and effective for the prevention and treatment of allergies; arthritis; blindness; cancer; cerebral palsy; chronic infections; colds; constipation; coronary thrombosis; deafness; dental caries; diabetes; diarrhea; digestive problems; distorted heart rhythm; dry skin, hair, and nails; emotional instability; epilepsy; fatigue; fear complex; functional and organic disease; headache; heart trouble; infantile paralysis; insomnia; loss of manual dexterity; loss of weight; lowered body efficiency; lusterless eyes; mental confusion; mental deficiency; mental illness; multiple sclerosis; muscular dystrophy; nephrosis; neuritis; poor blood coagulation; sinus trouble; skin inflammations; sores; tuberculosis; virus infections; and weakness; (b) the labeling contained representations that the article was a necessary and required adjunct to the diet because the average American person has a serious dietary deficiency of the vitamins and minerals supplied by the article; that consumption of protein in this country is far below the optimum requirement; and that the article contributed protein to the diet, which representations were false and misleading since the average American person's diet is not deficient in vitamins and minerals, consumption of protein in this country is adequate, and the article would contribute only trivial amounts of protein to the diet; (c) the labeling contained also false and misleading representations that use of the article would be a major step toward better living; that use of the article assured nutritional health; that use of the article was never contraindicated; that practically everyone in this country is suffering from, or is in danger of suffering from, a serious dietary deficiency of vitamins and minerals due to foods being grown on depleted soils, and due to the pasteurization, storage, canning, processing, refining, shipping, freezing, and cooking of foods; that the ingredients and components: Mycozyme, papain, rice polishings, rose hips, egg shell, oyster shell, prune concentrate, sea salt trace minerals, sea lettuce, mint leaves, sulfur, citrus peel and infusion, wheat germ, chlorophyll, montmorillonite, rutin, cabbage, parsley, watercress, alfalfa, boron, and nickel, provided exceptional nutritive value of unknown mysterious character to the article; that the great majority of people would be benefited by the addition of even small quantities of essential vitamins and minerals to their usual diet; that

vitamin and mineral supplements added years to one's life; and that vitamins and minerals aided in controlling weight; that the daily use of the article was necessary for good nutritional health, a more abundant vitality, and greater energy for work or play; that the article, by supplying alfalfa extract, would be as valuable an additive to human nutrition as was alfalfa when included in the ration of animals; that the extract of alfalfa contained in the article was a valuable factor in reproduction, growth, and development and increased resistance to infection in human beings, and had mysterious nutritive value beyond that of the known nutrient substances found in alfalfa; and that anyone who did not use the article would be likely to subject himself to prolonged inadequate nutrition which would adversely affect physical appearance, eyes, hair, emotional stability, vitality, growth, development, resistance to disease, ability to learn, and ability to succeed in business, trade, and profession; that the article was superior to all other vitamin-mineral supplements and was the only such supplement that was entitled to be called "therapeutic"; (d) that the statements in the labeling "When these tiny microscopic cells are robbed of vital MICRO-NUTRIENTS (vitamins and minerals) due to a deficient diet; or are damaged by poisons, bacterial invasions, parasites, etc., they become TIRED-INEFFICIENT or SICK. Unless the cause is corrected, either by supplementing the diet (if a lack of these MICRO-NUTRIENTS is the cause), or by professional treatment (in case of injury, functional or organic disease) these cells may finally become so sick, they will DIE!" were misleading since such statements suggested that dietary deficiencies in vitamins and minerals are a major cause of cell deterioration, sickness, and death, whereas, in an overwhelming majority of cases, cell deterioration, sickness, and death are due to causes other than dietary deficiencies in vitamins and minerals; (e) the statements in the labeling "We eat refined sugars and starches; such as, pies, cakes, bread, cereals, candy etc., as though our lives depended upon them! These sugars and starches represent over 50% of our total caloric intake, and are almost totally lacking in vitamins and minerals." were false and misleading since pies, cakes, bread, and cereals are not composed solely of refined sugars and starches, and they do contain material quantities of vitamins and minerals; (f) the statements in the labeling "Today MILLIONS of people EXIST in a sort of 'twilight zone' between health and illness being neither PHYSICALLY VITAL nor actually sick, but they accept this condition as 'good health' because they are not bedridden or because they have no evident clinical manifestations of disease. These people suffer from minor complaints rather than physical disorder. They complain of 'weakness' of 'being tired,' 'irritability' or 'digestive troubles.' Constipation, headaches, colds, 'virus infections' or other minor disorders are daily companions. If you are one of the millions putting up with these aggravating tiresome symptoms, and they are not due to external, organic or functional causes, there is great new hope shining through the window of science for you!" were misleading in that they failed to reveal the fact, material in the light of such representations, that in an overwhelming majority of cases such symptoms or conditions are due to external, organic, or functional causes; (g) the labeling contained the statements: "VI-SAN contains many, many different factors to supply a most complete balanced formula. If you're an 'average person' it's very possible you have one or more deficiency symptoms due to a diet that has not been adequate in MICRO-NUTRIENTS, essential vitamins and minerals, for a prolonged period of time. On the following page you will find

a list of deficiency symptoms. Check them and you will probably quickly realize the need for a QUALITY dietary supplement. CHECK LIST OF DEFICIENCY SYMPTOMS It must be realized that while these conditions can be brought about by prolonged multi-vitamin and mineral deficiencies, they can also be due to external causes, or to organic or functional diseases not related to nutritional deficiencies. Fatigue Lethargy or weakness Lowered body efficiency Hypersensitivity to noise Distorted heart rhythm Skin spots or inflammation Dim night vision Emotional irritability Digestive Upsets Muscular weakness Mental confusion Nervousness Loss of weight Depression Dental caries Loss of muscle tone Dizziness Irritation of gums Constipation Loss of appetite Loss of manual dexterity Rough dry hair and skin Diarrhea Headache Fear complex Insomnia Neuritis Sores on corners of lips Swelling and redness of tongue Eyes sensitive to light Anemia Slow healing cuts Poor blood coagulation Multi-vitamin and multi-mineral supplementation will not, of course, remedy diseases not due to nutritional deficiencies. However, a nutritional deficiency does retard the body's ability to overcome both acute and chronic conditions," which statements were false and misleading in that they suggested that the average person with any such symptoms very possibly could obtain relief by the use of Vi-San, whereas in the overwhelming majority of cases, most such symptoms and conditions are due to external causes or to organic or functional diseases, and not to nutritional deficiencies.

PLEA: Nolo contendere.

DISPOSITION: 4-25-60. \$1,500 fine.

6215. Cowlserpa (reserpine) tablets, atropine sulfate tablets, digitalis tablets, and Salamin tablets. (F.D.C. No. 42435. S. Nos. 64-348 M, 8-544 P, 8-785 P, 11-955 P.)

INFORMATION FILED: 4-30-59. Dist. Mass., against Cowley Pharmaceuticals, Inc., and Benjamin (Ben) C. Cowley, president, Auburn, Mass.

SHIPPED: Between 7-19-57 and 3-12-58, from Massachusetts to New York and Michigan.

LABEL IN PART: "1000 Tablets COWLSERPA (Brand of Reserpine) \* \* \* Distributed and Sold Exclusively by ZIEGLER PHARMACAL CORP. BUFFALO 2, N.Y. 6531"; "45,000 Tablets ATROPINE SULFATE" [or "5000 TABLETS DIGITALIS RED" or "1000 tablets SALAMIN PAS TIMED DIS-INTEGRATION] \* \* \* COWLEY PHARMACEUTICALS, INC."

CHARGE: 502(a)—the statements on the labels of the articles, namely, (*Cowlserpa tablets*) "Each tablet contains: Reserpine 0.25 mg.," (*atropine sulfate tablets*) "Each Tablet contains: Atropine Sulfate  $\frac{1}{300}$  gr.," and (*digitalis tablets*) "Digitalis \* \* \*  $1\frac{1}{2}$  gr." were false and misleading since each *Cowlserpa tablet* contained less than 0.25 milligram of reserpine, each *atropine sulfate tablet* contained less than  $\frac{1}{300}$  grain of atropine sulfate, and each *digitalis tablet* contained less than  $1\frac{1}{2}$  grains of digitalis; and the statement on the label of the *Salamin tablets*, namely, "Each tablet contains: 0.5 gm. Para-Aminosalicylic Acid Dihydrate For a timed release over a period of 6-8 hours," was false and misleading since each *Salamin tablet* failed to release 0.5 gram of para-aminosalicylic acid in an 8-hour period.

The information alleged also that another product, namely, Metavites tablets, was misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.